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## REMARKS/ARGUMENTS

## I. Status of the Claims

Claims 1-7 and 8-53 remain in this application. Claim 8 has been canceled. Claims 5, 6, 10-13 and 16-52 have been withdrawn as the result of an earlier restriction/election of species requirement. New claim 53 has been added. Support for new claim 53 can be found in the specification at least at page 7, 4<sup>th</sup> paragraph and page 10, 2<sup>nd</sup> paragraph.

## II. Continuity Data

## III. Claim Rejections - 35 U.S.C. § 102

The Examiner has rejected claims 1-4, 8, 9, 14 and 15 as allegedly anticipated by U.S. Patent No. 5,753,637 ("Fried"). Applicants respectfully traverse this rejection.

Applicants claimed invention relates to a method for reducing the number and severity of acne lesions on the skin of a mammal. The method comprises the step of administering a sensory regimen in an amount effective to downregulate the activity of the HPA axis of said mammal in combination with the administration of an anti-acne composition comprising an effective amount of an anti-acne agent. The sensory regimen is selected from the group consisting of auditory stimuli, visual stimuli, tactile stimuli, gustatory stimuli and olfactory stimuli, and combinations thereof and is effective to downregulate the activity of the HPA axis and wherein said activity of the HPA axis is downregulated by at least one of the following methods: (1) reducing the amount of total daily adrenocortical hormone; (2) reducing adrenocortical hormone at any time point in the period from about 4 to about 8 hours following morning waking; (3) reducing the total daily adrenocortical hormone minus the integrative measure of morning peak adrenocortical hormone.

Applicants have discovered that currently available commercial acne products can be significantly improved through the administration of the sensory regimen described above. Indeed, as shown by Example 1, the addition of an olafactory stimuli, i.e., relaxing fragrance, to benzoyl peroxide skin cream (Group 2), significantly improved the performance of the product as compared to the benzoyl peroxide skin cream without fragrance (Group 1). Such an improvement is neither taught nor suggested by Fried.

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Fried simply relates to a method for treating acne conditions comprising an acne treatment medicine with is benzoyl peroxide, i.e., comparable to Group 1 of Example 1 of Applicants application. There is no teaching or suggestion in Fried that the Fried composition could be improved by the administration of a sensory regimen as claimed by Applicants. The Examiner argues that Freid teaches the inclusion of inert carriers such as aloe vera gel and therefore anticipates the present claims. Applicants respectfully disagree.

Fried specifically states that "particular blends of carriers are not critical to the present invention, as long as they provide no interference with the activity of the acne treatment medication and the vasoconstrictor, and hence, are inert." See col. 3, lines 5-8.

Accordingly, Fried specifically teaches that aloe vera gel does not have any effect on the activity of the acne treatment. Further, Fried makes no mention of a sensory regimen which is effective to downregulate the activity of the HPA axis. The "inert carriers" which are "not critical" and "provide no interference" taught by Fried would simply not be effective to downregulate the activity of the HPA axis. Accordingly, Fried fails to anticipate the claimed invention.

# IV. Claim Rejections - 35 U.S.C. § 103

The Examiner has rejected claim 7 as allegedly unpatentable over Fried in view of U.S. Patent No. 5,466,446 ("Stiefel et al."). The Examiner relies upon Stiefel et al. for teaching the motivation of adding an antibacterial composition to the compositions of Fried. Applicants respectfully traverse this rejection at least for the reasons set forth above with respect to Fried, as Stiefel does not remedy the deficiencies of Fried.

## V. Conclusion

Applicants believe that the foregoing presents a full and complete response to the outstanding Office Action. An early and favorable response to this Amendment is earnestly solicited. If the Examiner feels that a discussion with Applicants' representative would be helpful in resolving the outstanding issues, the Examiner is invited to contact Applicants' representative at the number provided below.

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If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 10-0750/JBP-534/EMH. If a fee is required for an Extension of time 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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Dated: January 26, 2004